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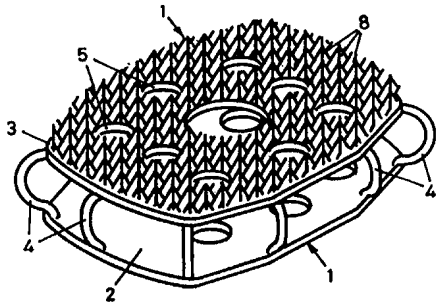
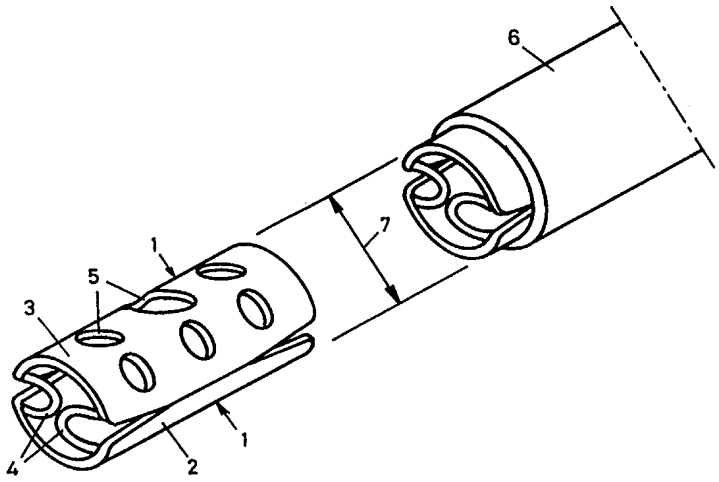
(54) Title: SURGICAL PROSTHETIC DEVICE

(57) Abstract

The surgical prosthetic device is adapted for placement between two adjoining vertebrae for total or partial replacement of the disk from therebetween. The device has two plates (1) with interior surfaces (2) facing each other and being held at a distance by connecting means (4), and exterior surfaces (3) destined for contacting the end plates (1) of the two adjoining vertebrae, whereby the connecting means (4) are made of a shape–memory alloy. Both end plates (1) may also be made of a shape–memory alloy, e.g. nitinol. The device is introducible between two adjoining vertebrae endoscopically (6).





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SURGICAL PROSTHETIC DEVICE

This invention concerns a device in accordance with the preamble of claim 1.

It is a well-known surgical procedure to remove a damaged disc in the spine between two adjacent vertebrae of patient and to replace it by inserting into the resulting disc space one or more implants having a combined width approximating the height of the disc space. The implant must be able to maintain the space between the two adjacent vertebrae.

Implantation of the surgical prosthetic device in the intervertebral space involves a considerable invasiveness with loss of or damage of anatomical structures.

The invention as claimed aims at solving the above described problems.

The present invention provides a surgical prosthetic device as defined in claim 1.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming part of this disclosure. For the better understanding of the invention, its operating advantages and specific objects attained by its use, reference should be had to the accompanying drawings, examples and descriptive matter in which are illustrated and described preferred embodiments of the invention.

In the drawings:

Fig. 1 is a perspective view of a device according to the invention at a temperature below the transition temperature of the memory alloy;

Fig. 2 is a perspective view of a modification of a device according to the invention at a temperature below the transition temperature of the memory alloy;

Fig. 3 is a perspective view of the device according to Fig. 1 at a temperature above the transition temperature of the memory alloy;

Fig. 4 is a perspective view of a modification of a device according to the invention at a temperature below the transition temperature of the memory alloy being applied by means of an endoscope; and

Fig. 5 is a perspective view of the device according to Fig. 4 at a temperature above the transition temperature of the memory alloy.

Fig. 1 shows a surgical prosthetic device adapted for placement between two adjoining vertebrae after removal of the disk from therebetween.

The device basically consists of two rectangular plates 1 with interior surfaces 2 facing each other and exterior surfaces 3 destined for contacting the end plates of the two adjoining vertebrae. The two plates 1 are held at a distance by connecting means 4 made of a shape-memory alloy having a transition temperature preferably in the range of 5°C - 30°C (15°C - 25°C being the optimal range).

A range of known shape-memory alloy is suitable for the connecting means 4, i.e. nitinol. Nitinol is a nearly equal ratio of nickel and titanium which exhibits a shape-memory effect. That is, after being deformed (up to 8 % strain) the material remembers its original annealed shape and will return to that original shape when heated above the shape transition temperature. In so doing, the alloy converts heat energy into mechanical work. The mechanical work done while the material is undergoing shape recovery can be much greater than that originally imparted during the initial plastic deformation. In order for an alloy to exhibit the shape-memory effect, it must be a crystalline structure which can shift into the so-called parent phase when it is subjected to a certain temperature

condition and then shift into the configuration known as martensite when the temperature is lowered. The alloy is first annealed to a specified shape. The alloy may then be heated to a temperature high enough that the crystalline structure assumes the parent phase or which is referred to in the art as the austenite configuration. Next the alloy is cooled until it reverts to the martensite configuration. The alloy may now be further deformed randomly but will return to the original shape when heated to a temperature above that at which the martensite returns to the parent phase. The specific transitional temperature at which the phase transition occurs can be controlled by controlling the exact nickel to titanium ratio.

The connecting means 4 in the device according to Fig. 1 are wires or other suitable longitudinal thin elements. The geometrical configuration of the connecting elements 4 at a temperature below the transition temperature is such that the two plates 1 are held at a reduced distance compared to their distance at a temperature above the transition temperature. The connecting means 4 may be distorted in various manners as shown in Fig. 1 (bent to the outside the device) or Fig. 2 (bent to the inside of the device).

The embodiment shown in Fig. 2 further differs from that of Fig. 1 in that the exterior surfaces 3 of the plates 1 are provided with a three-dimensional structure 8, e.g. in the form of small teeth or pyramids.

This distorted configuration of the connecting means 4 has the advantage that the device has a smaller volume below the transition temperature and therefore can be more easily introduced in the intervertebral space with less damage to the body tissues. After implantation of the device (held at a temperature below the transition temperature of the memory alloy, e.g. - 5°C) the body temperature (37°C) will heat up the device to a temperature above the transition temperature of the memory alloy and the device will get into a more voluminous configuration as shown in Fig. 3 which is designed to provide optimal spacing function for the two adjacent vertebrae.

A preferred embodiment of the invention is shown in Figs. 4 and 5, wherein the two plates 1 are also made of a shape-memory alloy. Preferably the two plates 1 (at a temperature below the transition temperature) have a hollow cylindrical configuration, their concave sides being connected by said connecting means 4.

As shown in Fig. 4 the shape of its exterior profile is generally circular when the device is below the transition temperature of the shape-memory alloy and generally rectangular (Fig. 5) when the device is above the transition temperature of the shape-memory alloy. This configuration of the profile of the device according to Fig. 4 allows the introduction of the device into the intervertebral space by means of an endoscope 6 - as indicated in Fig. 4 - having a tubular width 7

corresponding to the circular profile of the device according to Fig. 4. Typically the circular profile of the device has a diameter of approximately 20 mm.

In all embodiments of the invention the plates 1 may be provided with perforations 5 in order to facilitate bone ingrowth.
Furthermore the exterior surfaces 3 of the two plates 1 (of all embodiments) can be provided with a three-dimensional structure 8, e.g. small teeth or pyramids (Fig. 2) or similar structural elements in order to enhance fixation of the plates 1 to the end plates of the adjacent vertebrae.

The method of implanting the device according to the invention is now described referring to the embodiment according to Fig. 4 and 5.
The spacing device according to the invention is introduced into the space between two adjacent vertebrae after removal of the disk from therebetween at a temperature (e.g. 0°C) lying below the transition temperature of the shape-memory alloy of which the device is partially or totally made. As shown in Fig. 4 introduction is best done by means of a tubular endoscope 6. After insertion the spacing device is allowed to reach transition temperature (e.g. 20°C) and its predetermined configuration - as shown in Fig. 5 - suitable to its spacing function.

While the foregoing description and drawings represent the preferred embodiments of the present invention, it will be obvious for those skilled in the art that various changes and modifications may be made therein without departing from the true spirit and scope of the present invention.

Claims

1. A surgical prosthetic device adapted for placement between two adjoining vertebrae for total or partial replacement of the disk from therebetween, said device having two plates (1) with

- interior surfaces (2) facing each other and being held at a distance by connecting means (2); and
- exterior surfaces (3) destined for contacting the end plates of the two adjoining vertebrae,

characterized in that

the connecting means (4) are made of a shape-memory alloy.

2. Device according to claim 1, characterized in that the connecting means (4) are wires.

3. Device according to claim 1 or 2, characterized in that the two plates (1) are also made of a shape-memory alloy.

4. Device according to one of the claims 1 to 3, characterized in that the transition temperature of the shape-memory alloy is in the range of 5°C to 30°C, preferably between 15°C to 25°C.

5. Device according to one of the claims 1 to 4, characterized in that the shape-memory alloy is nitinol.

6. Device according to one of the claims 3 to 5, characterized in that the two plates (1) have a hollow cylindrical configuration, their concave sides being connected by said connecting means (4).

7. Device according to claim 6, characterized in that the shape of its exterior profile is generally circular when the device is below the transition temperature of the shape-memory alloy and generally rectangular when the device is above the transition temperature of the shape-memory alloy.

8. Device according to one of the claims 1 to 7, characterized in that the two plates (1) are provided with perforations (5)

9. Device according to one of the claims 1 to 8, characterized in that the exterior surfaces (3) of said plates (1) are provided with a three-dimensional structure (8), preferably in the form of teeth.

10. Device according to one of the claims 1 to 9, characterized in that two plates are closer to each other when the device is below the transition temperature of the shape-memory alloy than when the device is above the transition temperature.

11. Device according to one of the claims 1 to 10, characterized in that its exterior shape at a temperature below the transition of the shape-memory alloy is adapted in such a way that it is introducible between two adjoining vertebrae endoscopically.

12. A method of maintaining the space between two adjacent vertebrae of a patient after removal of the disk from therebetween comprising the steps of:

- inserting a spacing device made at least partially from a shape-memory alloy into the space between two adjacent vertebrae after removal of the disk from therebetween at a temperature below the transition temperature of the shape-memory alloy;
- allowing the spacing device to reach transition temperature and a predetermined configuration suitable to its spacing function.

Fig.1

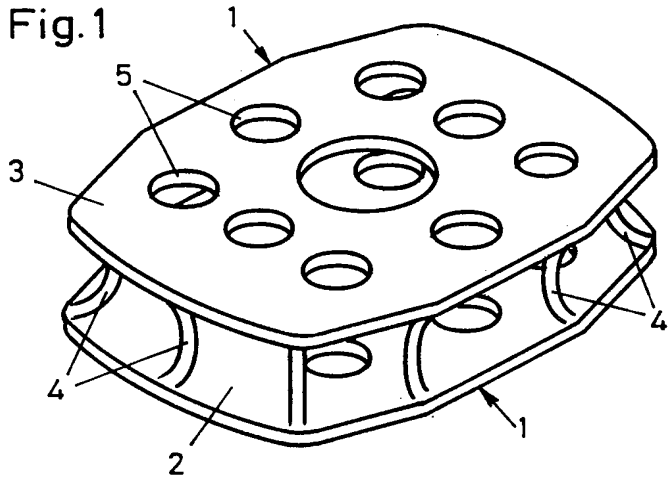


Fig. 2

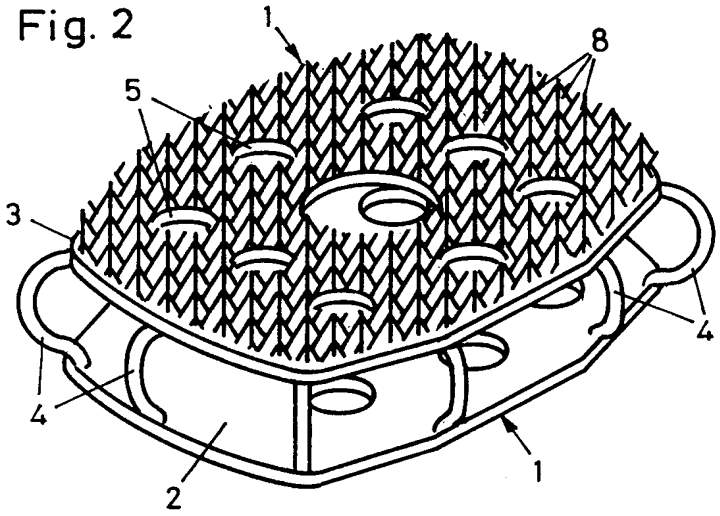


Fig. 3

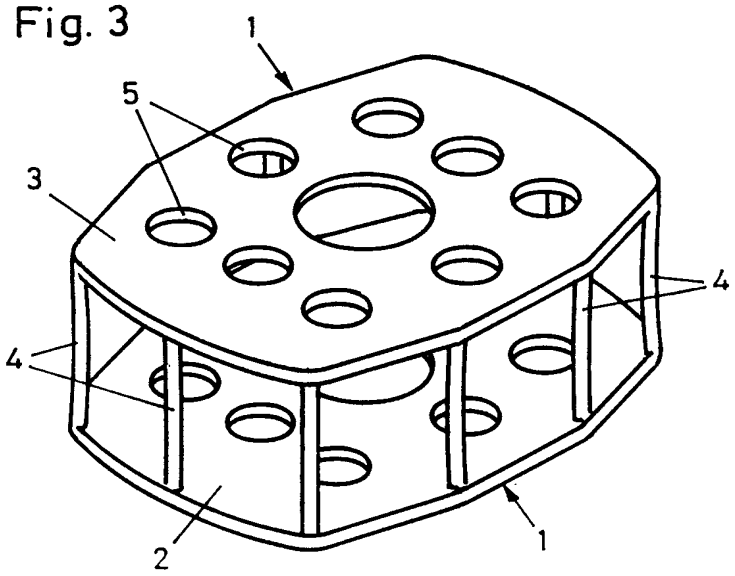


Fig. 4

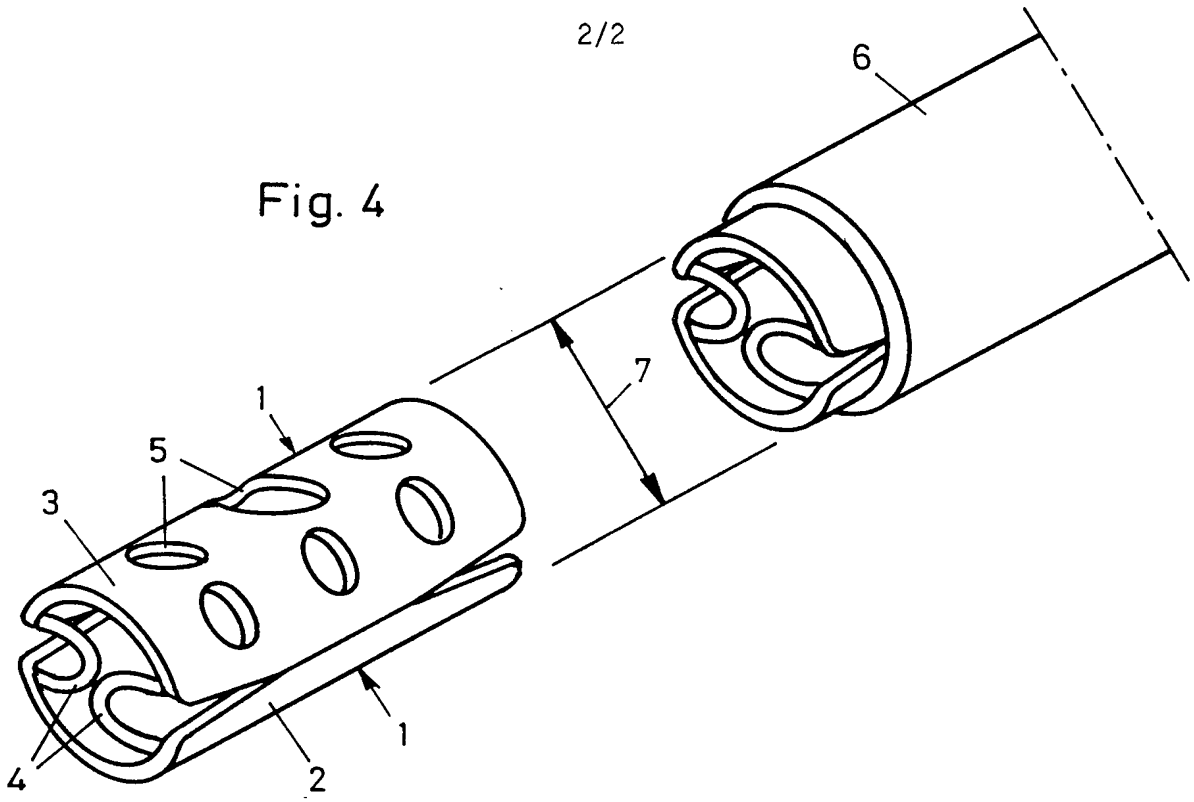
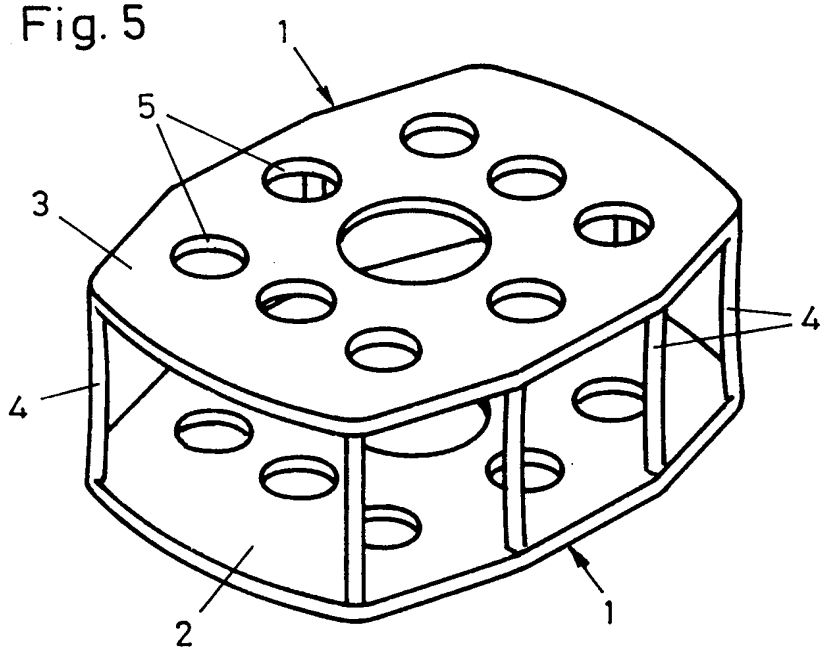


Fig. 5



INTERNATIONAL SEARCH REPORT

Inte nal Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/44 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	DE 94 13 778 U (SCHÄFER MICOMED) 4 January 1996 see page 8, line 8 - line 16; claims 1,5,6; figures ---	1,4,9,11 2,7,8
Y A	FR 2 712 486 A (BRESLAVE) 24 May 1995 see page 5, line 2 - line 17 see page 6, line 7 - page 7, line 30; claims 9,10,13; figures ---	1,4,9,11 3,10
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[X] Further documents are listed in the continuation of box C.

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